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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/989,881	12/12/97	SHEEN J	08472/716002

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EXAMINER	
ZAGHMOUT,O	
ART UNIT	**PAPER NUMBER**
1638	17

DATE MAILED: 08/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/989,881	Sheen
Examiner	**Group Art Unit**
Ousama Zaghmout	1638

☒ Responsive to communication(s) filed on *Apr 17, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-7, 24-26, and 36-46* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-7, 24-26, and 36-46* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *13*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

STATUS OF APPLICATION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The amendment filed 04/17/2000 has been received (Paper No. 16).

4. The declaration submitted by Dr. Jen Sheen (Sheen's declaration) has been received (Paper No. 15).

4. Status of the claims:

Claims 8-23, 27-35, and 47-48 have been canceled by Applicants (Paper NO.16).

Claims 1, 6, 7, 24, 36-39, and 42 have been amended.

Claims 1-7, 24-26, 36-46 are pending.

5. The affirmation of the election of Group I, claims 1-7, 24-26, and 36-46 by Applicant is noted.

Claim Rejections-35 U.S.C. 101

1. The rejection of Claim 36 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter has been withdrawn upon further consideration of the record and applicant's response.

Claim Rejections - 35 USC § 112

Claims rejection - Ist paragraph

1. Claims 1-7, 24-26, 36-39, 41-46 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants arguments filed on 04/17/2000 have been carefully considered, but not found to be persuasive.

A. The citation of case laws by Applicant (paragraph 2, page 6 of the Remarks) is of no help as the specification does not contain the written description of the claimed subject matter. In that respect, the specification does not provide the physical characteristics or the chemical properties that describes any protein kinase (PK) domain-containing gene isolated from a plant. Furthermore, neither the specification nor the prior art can predict the functional or the structural characteristics of PK genes from other plant species. Subsequently, Applicants were not in a possession of a method for protecting plant against any environmental stress by transforming with any recombinant protein kinase (PK) domain-containing gene isolated from any plant, any transgenic plants and any seeds thereof. The specification provides only the PK

gene isolated from Arabidopsis thaliana as shown in SEQ ID:1. Applicant has not disclosed PK genes isolated from other plant species. Subsequently, a person with skill in the art could not have predicted the functional or the structural characteristics of PK genes in transgenic plants. Accordingly, one of skill in the art would not have recognized the applicant to have been in possession of the claimed subject matter at the time the application was filed. As such, this application did not satisfy the written description requirement. To satisfy the written description requirement, Applicants must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed invention.

B. The Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling. The separateness of the two requirements has been emphasized in the biotechnology area by two cases. Both cases involved interferences in which the count in question related to a strand of DNA. In one case Fiers v. Sugano [25 USPQ2d 1601 (Fed. Cir. 1993], :"An adequate description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself." In the Fiers case, convention priority was denied to a claim to a DNA sequence coding for a specified protein because of the absence of

the actual sequence of the DNA in the priority documents. A similar situation occurred in Fiddes v.Baird [30 USPQ2d 1481 (Bd. of Appeals 1993).] where the Board of Appeals stated that "knowledge of amino acid sequence of a protein coupled with the established relationship in the genetic code between a nucleic acid and a protein it encodes would not establish possession of a gene encoding that protein."

C. Applicant argue that the specification explicitly describes to those skilled worker what is claimed (e.g., pages 10-11, 36-37) which describe methods for producing stress tolerant plant; pages 16-22 which describe a stress-signaling pathway and constructs useful for generating plants having tolerance to an environment stress; Example shown in Figure C; pages 13-15 which describe how to select PK domains active in stress signaling). This is not found persuasive as the case law mentioned above made it clear that there is a difference between the requirement of enablement and written description. In the instant application, the specific does not provide the physical characteristics or the chemical properties of any substantially pure DNA encoding any PK domain polypeptide isolated from any plant in order to claim the genus at the time when the application was filed. The Example shown in Figure 3C of all were isolated from Arabidopsis thaliana and do not represent the genus.

2. Claims 1-7, 24-26, 36-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolation of PK gene from Arabidopsis thaliana as shown in SEQ ID:1, does not reasonably provide enablement of a method for protecting

plant against an environmental stress by transforming with any recombinant protein kinase (PK) domain-containing gene whereby said plants have an increased tolerance to an environmental stress. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons of record stated in the previous Office action.

Applicant's arguments and Declaration of Dr. Jen Sheen (Dr. Sheen's declaration) filed on 04/17/2000 have been carefully considered but not found persuasive.

A. The Example provided in Dr. Sheen's declaration is enabled only for a method for producing transgenic plants that are drought tolerant as a result of the overexpression of the nucleotide sequence encoding AtCDPK1 when was operably linked to 35 S promoter. However, Dr. Sheen's declaration does not enable the invention as claimed where the methods of the invention are drawn to any method for producing transgenic plants that are drought tolerant as a result of the overexpression any PK domains-containing gene isolated from any source including Arabidopsis thaliana. As stated in the previous office action, neither the specification nor the art shows that the nucleotide sequences of PK domains-containing genes are identical. In fact, the art shows the contrary. Additionally, the specification did not provide those skilled in the art guidance as which amino acids could be changed without losing the activity of the protein because a very small change in the amino acid sequence of a protein can

result in a very large change in the structural-functional activity of a protein. Subsequently, it is unpredictable if the nucleotide sequences claimed but not exemplified in the specification will be have the same functional properties and/or confer the drought tolerant phenotype upon overexpression in any transgenic plant. As such, the citation of In re Marzocchi (as cited in paragraph 1, page 9 of the Remarks) of no help to Applicants in overcoming the rejection as claimed in this instant application.

Moreover, drought is only one type of environmental stress. Other types of environmental stress include, but not limited to, high and low temperature, salinity, heavy metal elements and high ozone concentration in the atmosphere. Applicant has exemplified resistance only to a single environmental stress (e., drought) which does not commensurate in scope with "environmental stress" as claimed. The correlation between drought resistance and resistance to many diverse stresses that fall within the scope of the claims has not been established and it can not be predicted that PK1 domain will confer similar resistance to the large number of diverse stresses that fall within the scope of the claims as now written. In addition, it is well known in the art that proteins involved in each type of these types of stress are quite distinct. In that respect, the ability of plants to tolerate high temperature is directly related to the accumulation of heat shock proteins. On the other hand, drought resistance is mediated by an increase in the level of abscisic acid in the plant, not by accumulation of heat shock proteins. This unpredictability is further supported by the specification that the effects of CDPK1 And CDPK2 are specific since six distinct plant protein kinases, including two

other CDPKs, fails to mimic stress signaling (see last paragraph of page 12 of the specification). This unpredictability is further supported by the teaching of Urao et al (Mol. Gen Genet (1994), Vol:244:331-340; A reference was sent to Applicant in the previous Office action). In that respect, Urao et al teach that ATCDPK1 and ATCDPK2 are not induced by either low (4 °C) or high temperature (40 °C) (see Fig.2, lanes e and d in the Northern blot; see also lines 22-23, column 1, page 338). Those skilled in the art recognize that low and high temperature stress are part of the environmental stress as encompassed by the claims (e.g., claim 1). ATCDPK1 and ATCDPK2 are substantially pure DNA encoding a polypeptide that includes protein kinase domain.

Thus, in absence of guidance from the specification as to what structural features impart this property and the majority of exemplified embodiments lack this property and the number of embodiments falling within the scope of the claim is extremely large, these factors will help support a conclusion of undue experimentation. Thus, it is unpredictable if transgenic plants produced in the instant invention, will also be resistant to other types of stress including high temperature.

B. Applicants argue that the invention is enabled as claimed since it does provide guidance for isolation of additional PK domain encoding genes (e.g., pages 16-20, Figures 3 B and 3C, pages 22-24), generating expression constructs (e.g., pages 24-31 and 36-37), how to express and test such sequences in plants (e.g., pages 13-14) and in conferring tolerance to environmental stress in plants (last paragraph of page 9 extending to paragraph 1 of page 10 of

the Remarks). Applicants further argue that the specification describes several methods for introducing the vectors into plant cells (e.g., pages 28-31) and that transgenic plants expressing said genes can be selected by visual examination (e.g., wilting) as shown in the declaration (cited in paragraph 1, page 11 of the Remarks). Applicants conclude these arguments by citing a number of case laws including In re Wands as cited in paragraph 2, page 11 of the Remarks that " a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." This is not found persuasive for a number of reasons: first, the scope of the invention is very broad and encompasses large number of PK domain-containing genes, many of which have not even been isolated nor tested at any level in any cell in any plant. Second, as stated in the previous office action, the production of transgenic plants with desirable traits such as drought in any plant by overexpression of any PK-domain-containing gene from any source is unpredictable. Applicants have not shown that any PK-domain containing gene would be able confer such traits upon expression in a transgenic plant. Third: the number of examples provided in the specification is very limited to the expression of one single gene (AtCDPK1) isolated from one single plant species, namely, Arabidopsis thaliana. In order to be able to claim the genus, a representative number of species which covers the genus need to be exemplified by applicants either in the specification or provided through a declaration. Fourth: the amount of direction or guidance presented was not directly related to the claimed invention as for

example, the specification failed to teach those skilled in the art how to use any PK-domain containing gene as claimed to confer tolerance to environmental stress. This is essential for the enablement of the invention as claimed since the claims encompass large number genes that are different in the physical characteristics and the chemical properties. Fifth: It should also be noted that all of the factors of In re Wands (as cited in paragraph 2, page 11 of the Remarks) need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

C. The citation of W. L. Gore & Assoc. V. Garlock, Inc (see paragraph 1, page 12 of the remarks) is misplaced by Applicants as the expression of transgene in transgenic in plant is unpredictable and the scope of the claimed subject matter n this application is very broad which entails the testing of large number of genes which contain PK domain from any source in any plant.

Therefore, in view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner' position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentations. Subsequently, the rejection is maintained..

2nd Paragraph

1. The rejection of Claim 5 under 35 U.S.C. 112, second paragraph, as being vague for the recitation of the words " multiple stress conditions" has been withdrawn upon further consideration of records and Applicant's response.

2. The rejection of Claim 6 under 35 U.S.C. 112, second paragraph, as being vague for the recitation of the words " activates the expression of a stress-protective protein" has been withdrawn upon further consideration of the records and Applicant's response.

3. The rejection of Claim 7 under 35 U.S.C. 112, second paragraph, as being vague for the recitation of the words " constitutively expressed" has been withdrawn upon further consideration of the records and applicants' response.

Claim Rejections - 35 USC § 102

1. Claims 36-46 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Urao et al [Mol. Gen. Genet. 1994. 244: 331-340] for the same reasons of record mentioned in the previous Office action.

Applicant argue that since claim 36 has been amended to include the limitation "consisting essentially of a PK domain". This is not found to be persuasive as the limitations in the claims are still read in the reference. In that respect, the reference teaches nucleotide sequence and deduced amino acid sequences of two cDNAs, cATDPK 1 and cATDPK2

isolated from Arabidposis plants which appear to be identical to the nucleotide sequence disclosed in SEQ ID:1 (Figure 3A,B, page 334; see also Materials and Methods, paragraph 3-5, page 332). The sequences taught by the reference a DNA molecule that encodes a polypeptide consisting essentially of a PK domain. As such, the rejection is maintained.

Claim Rejections - 35 USC § 103

1. The rejection of claims 1-7, 24-26 under 35 U.S.C 103 (a) as being unpatentable over Urao et al [Mol. Gen. Genet. 1994. Vol. 244: 331-340] taken with Gordon-Kamm et al (The Plant Cell. 1990. Vol. 2: 603-618) has been withdrawn upon further consideration of the record and Applicant's arguments.

2. The rejection of claims 36-37, 40-46 under 35 U.S.C 103 (a) as being unpatentable over Urao et al [Mol. Gen. Genet. 1994. Vol. 244: 331-340] taken with Gordon-Kamm et al (The Plant Cell. 1990. Vol. 2: 603-618) has been withdrawn upon further consideration of the record and Applicant's arguments.

CONCLUSION

No claims are allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.
June 27, 2000

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER